



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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HF1-35
Public Health Service

PKLN
Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
Facsimile: 504-253-4560

April 6, 2001

WARNING LETTER NO. 2001-NOL-19

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Ms. Sandra E. Collier, President
Elliott's Produce Company, Inc.
2278 Halls Mill Road
Mobile, Alabama 36606

Dear Ms. Collier:

The U.S. Food and Drug Administration (FDA) inspected your food storage warehouse facility, located at 2278 Halls Mill Road, Mobile, Alabama, during March 14-15, 2001. During the inspection, our investigator documented numerous insanitary conditions, which caused the food products stored at your facility to become adulterated. The adulterated food products are in violation of Sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they consist in whole or in part of filthy substances, including rodent fecal pellets, and had been held under insanitary conditions whereby they may have become contaminated with filth.

Evidence of rodent activity was observed in, on, and near foods stored in your warehouse and associated coolers. This evidence included rodent excreta pellets, rodent urine stains, and gnawed food products. Evidence of rodent gnawing was observed on several different food products including honeydew melons and carrots. Our FDA laboratory confirmed the findings of rodent excreta sampled from your facility during the inspection.

Our investigation of the general storage conditions in the warehouse revealed: an approximate 1/2" x 7" opening to the outdoors at the bottom of the east wall and an approximate 3/4" x 4" opening to the outdoors at the bottom of the north wall in cooler number nine; an approximate 3/4" x 2' opening at the bottom of the west wall in warehouse number two; and, an approximate 2 1/4" x 1" opening to the outdoors at the bottom of the east wall in warehouse number two, cooler number one.

Other conditions documented during the inspection include observations of live birds and cats on and near foods stored in your warehouse.

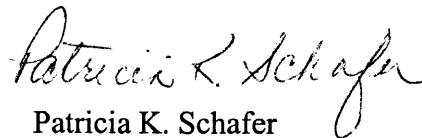
The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to insure that your facility is operated in a sanitary manner.

At the conclusion of the inspection, our investigator presented to you a list of deficiencies on a Form FDA 483, List of Inspection Observations. You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure, injunction, or prosecution.

You should notify this office, in writing, within 15 days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, please state the reason for the delay and the time by which the corrections will be completed.

Your response should be directed to Rebecca A. Asente, Compliance Officer, U.S. Food and Drug Administration, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. Should you have any questions concerning the contents of this letter, you may contact Ms. Asente at (504) 253-4519.

Sincerely,

A handwritten signature in cursive script that reads "Patricia K. Schafer". The signature is written in dark ink and is positioned above the printed name and title.

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483